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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/529,734	06/19/2000	GILBERT THEO HINZE	23739	3227
759	90 04/08/2003			
NATH & ASSOCIATES 1030 15TH STREET NW SIXTH FLOOR			EXAMINER	
			PAK, JOHN D	
WASHINGTON, DC 20005			ART UNIT PAI	
			1616	·
			DATE MAILED: 04/08/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		09/529,734	HINZE, GILBERT THEO			
		Examiner	Art Unit			
		JOHN D PAK	1616			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address					
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM						
THE I - Exter after - If the - If NO - Failul - Any r earne	MAILING DATE OF THIS COMMUNICATION.  Insions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply in period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).			
Status						
1)⊠						
2a)⊠ —	<i>,</i> —	is action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)🖂	4) Claim(s) 9-12,14-16,18 and 19 is/are pending in the application.					
,	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>9-12,14-16,18 and 19</u> is/are rejected.						
7)	7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.						
	on Papers					
9) The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)⊠ All b)□ Some * c)□ None of:						
1.☐ Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3.⊠ Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>						
Attachment(s)						
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)			

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Claims 9-12, 14-16 and 18-19 are pending in this application. This Office Action is in response to applicant's reply of 1/17/03.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-12, 19 are rejected under 35 U.S.C. 102(b) as anticipated by Bakhir et al. (US 5,427,667) for the reasons previously set forth with respect to claim 10 in the last Office Action (Paper No. 9). Note, claims 12 and 19 could not be examined on the merits in the last Office Action because they were dependent on a canceled claim.

As discussed in Paper No. 9, Bakhir et al. explicitly disclose numerous electrolyzed anolyte solutions that have redox potential ranging from 630 to 1200 mv (see columns 9-10, Table 2). Bakhir et al. disclose that it is known to use the anolyte solution from electrolyzed salt water as disinfecting solutions in medicine (column 1, lines 38-42).

Independent claim 10 has been amended in applicant's reply of 1/17/03 to recite a product-by-process feature for the composition. The electrochemically activated anion-

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containing aqueous solution is produced by an electrochemical reactor including:

(i) a through-flow, electrochemical cell having

(ii) two co-axial cylindrical electrodes with

(iii) a co-axial diaphragm between the electrodes so as to separate an annular inter-

electrode space into a cathodic and an anodic chamber.

As shown by the below discussion and analysis of Bakhir's teachings, all such features are explicitly disclosed or encompassed in Bakhir's composition.

## (i) A through-flow, electrochemical cell

Bakhir's cell is an electrochemical cell (column 2, lines 57-58). The through-flow feature is clearly encompassed by Bakhir's electrochemical cell because it treats a supply of water and discharges it (column 2, line 63 to column 3, line 6; column 11, lines 30 and 38, "flow through"). Therefore, the ordinary meaning of "through-flow" is disclosed and encompassed by Bakhir's electrochemical cell.

## (ii) Two co-axial cylindrical electrodes

Bakhir's electrodes are explicitly disclosed as "vertical coaxial cylindrical and rod electrodes" (column 2, lines 58-59). See also column 7, lines 31-34. This feature is clearly and explicitly disclosed.

## (iii) Co-axial diaphragm between the electrodes so as to separate an annular inter-electrode space into a cathodic and an anodic chamber

Bakhir's diaphragm is "coaxially mounted in the sleeves between said electrodes and dividing the electrodes spacing into electrode chambers" (column 2, lines 59-62). The diaphragm's coaxial arrangement with the cylindrical electrodes is again emphasized (Example

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1, column 7, lines 31-34). The term "co-axial" means having a common axis. Bakhir's electrochemical cell certainly teaches coaxial diaphragm, as claimed by applicant.

For these reasons, the new amendatory language in independent claim 10 does not change the determination that Bakhir et al. anticipate claim 10. As for claims 11-12 and 19, Bakhir et al. explicitly disclose redox potential of +630 to +730 mv for solutions resulting from mineralized water that is supplied to the above described electrochemical cell (see from column 9, line 19 to end of Table 2 on column 10). Salt is contained in minerals (see column 11, line 30-32).

The Examiner cannot understand why applicant highlighted "an upright cylindrical electrode" on page 13 of his 1/17/03 reply (Paper No. 11) in discussing Bakhir et al. Perhaps applicant is confusing co-axial cylindrical electrodes as not being readable on upright cylindrical electrode. Applicant is mistaken. All that "co-axial" means in the present context is having a common axis. Applicant has not provided a specialized definition. Bakhir et al. clearly teach coaxial configuration of the cylindrical electrodes and the diaphragm (column 2, lines 59-62; Example 1, column 7, lines 31-34).

Applicant argues in the same Paper No. 11 that a composition for the preparation of a medicament for use in the treatment of pathogenic microorganisms in a live animal is not disclosed by Bakhir et al. The Examiner maintains that the same exact process was used by Bakhir et al. and therefore the same product must necessarily be produced.

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The claims are thereby anticipated. The section 103(a) part of this ground of rejection will not be repeated here since the anticipatory ground is sufficient and the section 103(a) ground of rejection with combination of references incorporates the same rationale.

Claims 9-12, 14-16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakhir et al. in view of WPIDS abstract 1996-096021, Morrow, Imai, Fraser et al., VETU abstracts 1985-63045, 1988-60359, 1994-62049 and Kroschwitz et al.

All cited references have been discussed in the last Office Action (pages 8-12) and above in this Office Action. The discussion of the references are incorporated herein to avoid repetition. The disclosure by Bakhir et al. is relied upon as a primary teaching here because of the claim amendments that now require various electrochemical cell features.

It is without question that Bakhir et al. disclose the very same "electro-chemically activated anion-containing aqueous solution" as claimed and used by applicant in the claims. See the discussion on pages 2-4 of this Office Action. The secondary references provide further clarification of the art and motivation to utilize Bakhir's composition as claimed by applicant.

Bakhir et al. already teach that the anolyte solution from electrolyzed salted water as disinfection solutions in medicine (column 1, lines 38-42; see also column 12, lines 15-34). Further, Bakhir et al. teach that formation of active chlorine takes place in the anode chamber, thereby producing anolytes with active chlorine (column 11, lines 30-32).

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Bakhir et al. do not explicitly disclose their composition for treating pathogenic microorganisms in a live animal (method claim 9). Bakhir et al. also do not explicitly disclose their composition for treating respiratory and gastrointestinal pathogenic microorganisms in a live animal (method claims 14-16, 18).

However, the cited secondary references provide the motivation to utilize Bakhir's composition in the manner claimed by applicant in the method claims. WPIDS abstrct 1996-096021 disclose that analyte solution from electrochemical activation of aqueous solution of NaCl or KCl is a commercial product that is used in medicine, as a disinfectant for building interiors, to prevent intestinal and droplet-type infections of bacterial and viral etiology, in cases of candidosis, dermatomycosis, tuberculosis, etc. and also to protect newborn babies and small children from hospital infections. The analyte from electrochemical activation of salt water clearly has medicinal disinfecting uses. Further, Morrow teaches various modes of administration of electrolyzed sodium chloride solution (contains oxychlorine species such as hypochlorous acid and hypochlorite) to treat a host animal for a variety of pathogenic diseases and to keep water free from pathogenic organisms such as E. coli (see from column 3, line 28 to column 5, line 19; see from column 5, line 56 to column 6, line 19; Examples I, IV, X-XII, XVI, XVII; claims 1-6; column 9, lines 27-31). Modes of administration include intravenous, oral, vaginal, rectal, depending on the condition being treated. Clearly, administering anioncontaining electrolyzed salt solution to, on or in a live animal is fairly suggested from these teachings. The remaining secondary references teach the known benefit of utilizing certain of the oxychlorine species that are produced from electrochemical activation of salt water in

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variety of settings, such as spraying to open areas, food stuffs, as well as to people (Imai), disinfecting water supplies for pigs to control intestinal diseases (Fraser et al.), disinfecting to prevent or control diseases in pigs and chicken (the three VETU abstracts). The article by Kroschwitz et al. shows that the electrochemical cell of the type claimed by applicant is conventional electrolysis technology (see pp. 124-133, 135-140) that is known to produce oxychlorine species (pp. 133-135).

Therefore, the prior art provides sufficient motivation for the ordinary skilled artisan to arrive at the method claims, as well as the composition claims (which have already been rejected under section 102 as being anticipated by Bakhir et al.). The electrochemically activated anion-containing aqueous solution taught by Bakhir et al. would have been expected to possess sufficient microbicidal activity for in vitro and in vivo uses so that one having ordinary skill in the art would have been motivated to at least administer it by introducing it into drinking water, fogging to produce small droplet sizes (Imai teaches 70 um droplet size), or apply it to external body surfaces (e.g. vaginal, rectal: see Morrow, column 9, lines 29-31). From such administration, effective control of microorganisms as claimed would have been obtained. This is in fact consistent with applicant's specification protocol of treating, which actually encompasses controlling or preventing (see Experiments 1 and 2 on pages 6-8).

Applicant's arguments of 1/17/03 have been given due consideration but they were deemed unpersuasive. Applicant's arguments with respect to the electrochemical cell are totally erroneous, as Bakhir et al. used the same exact type of electrochemical cell to produce their

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anion-containing anolyte solution. The Examiner cannot understand why applicant highlighted "an upright cylindrical electrode" on page 21 of his response in discussing Bakhir et al.

Perhaps applicant is confusing co-axial cylindrical electrodes as not being readable on upright cylindrical electrode. Applicant is mistaken. All that "co-axial" means in the present context is having a common axis. Applicant has not provided a specialized definition. Bakhir et al. clearly teach coaxial configuration of the cylindrical electrodes and the diaphragm (column 2, lines 59-62; Example 1, column 7, lines 31-34).

Applicant makes other arguments about design elements and advantages of the electrochemical cell, but applicant should limit the arguments with respect to the features and process claimed, not some other features or process steps that are not claimed. The Examiner maintains that all design elements of the electrochemical cell that are claimed are specifically and explicitly taught by Bakhir et al.

Therefore, the claimed invention, as a whole, would have been <u>prima facie</u> obvious to one of ordinary skill in the art at the time the invention was made, because the prior art provides sufficient motivation to utilize the electrochemically activated anion-containing aqueous solution, as produced in accordance with the claimed process features, to treat pathogenic microorganisms in a live animal, as claimed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703)308-4556 or (703)305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner J. Pak, whose telephone number is (703)308-4538. The Examiner can normally be reached Monday through Friday, 7:00 AM to 3:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Jose Dees, can be reached on (703)308-4628. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

JOHN PAK RIMARY EXAMINER GROUP 1600